



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,878	03/15/2001	James H. Pickar	AM100226	5270

7590

03/12/2002

Egon E. Berg
American Home Products Corporation
Patent Law Department
Five Giralda Farms
Madison, NJ 07940

EXAMINER

BAHAR, MOJDEH

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 03/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/808,878

Applicant(s)

PICKAR, JAMES H.

Examiner

Mojdeh Bahar

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 15-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-14 and 69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment and response to the first office action of September 13, 2001, submitted December 13, 2001 (Paper No. 5) is acknowledged.

This application contains claims 1-6 and 15-68 drawn to an invention nonelected with traverse in Paper No. 5. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-14 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Plunkett et al. (USPN 4,826,831, RE 36,247)

Plunkett et al. (USPN 4,826,831) teaches a method of treating hot flushes comprising administering continuously and uninterruptedly both progestogen and estrogen in daily dosage units, see claim 1 and col.9 lines 34-40 in particular. Plunkett et al. (USPN 4,826,831) also teaches conjugated equine estrogen/medroxyprogesterone as one of the estrogen/progestogen combinations useful in its method, see claims 3, 5 and 8. Plunkett teaches the minimum and maximum dosages for medroxyprogesterone to be 1 mg/day and 15 mg/day respectively, see claim 4 in particular. Plunkett teaches the dosage range for Ethinyl estradiol to be between 0.005

Art Unit: 1617

and 0.020 mg/day, and the dosage range of quinestranol to be between 0.005 and 0.020 mg/day, see claim 5.

One of ordinary skill in the art would have been motivated to employ any of the estrogen/progestogen combinations taught in Plunkett in a method of treating hot flushes because they are known to be useful in methods of treating menopausal disorders including hot flushes.

Response to Arguments

Applicant's arguments regarding the non-obviousness of the claims have been considered but are not persuasive to remove the obviousness rejection. Applicant first argues that the prior art, Plunkett, discloses 20 estrogens and 17 progestins that can be combined. Applicant further argues that Plunkett provides a list of 20 "especially preferred" combinations. Applicant asserts that these disclosed species would give rise to "thousands of possible combinations of estrogens and progestins." Note that Plunkett exemplifies the exact estrogen-progestin combination herein, see in particular col.7 as well as claim 8.

Secondly, applicant refers to *In re Baird* as a case analogous to the case at bar. 29 USPQ2d 1550 (CAFC 1994). Note that the case at bar is distinguishable from *In re Baird* in that the exact estrogen-progestin combination claimed herein is exemplified by the prior art at col.7 as well as in claim 8. In *Baird* the court held that "disclosure of a generic formula that may encompass claimed compound does not, without more, render compound obvious." Note that Plunkett teaches **more than** a generic combination, it specifically teaches the estrogen-progestin combination claimed herein.

Thirdly, applicant argues that the dosage of the estrogen-progestin combination herein is lower than that of Plunkett. Note that the claimed 1.5 mg of medoxyprogesterone is within 1 mg-15 mg, the range taught in Plunkett see claim 4 in particular. Similarly the claimed dosage of 0.3 and 0.45 of conjugated estrogens falls within Plunkett's range of 0.300 mg to 2.5 mg, see Table IA, col.4.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

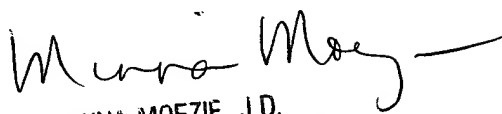
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from Monday to Friday from 9:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Art Unit: 1617

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
September 7, 2001


MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600